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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 29 1997

WARNING LETTER

Ref: OC: I4-1276

Via Federal Express

Mr. Lanny Schuberg
IDEC Corporation
1213 Elko Drive
Sunnyvale, California 94089-2211

Dear Mr. Schuberg:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) hereby disapproves the quality control and testing program for laser products produced by IDEC Corporation of Sunnyvale, California and IDEC/IZUMI Corporation of Japan. This action is taken under the authority of the United States' (U.S.) Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control (hereafter referred to as "the Act").

On March 2, 1995, this Agency sent you two letters. The first declared that laser products imported by your firm failed to comply with the Federal performance standard for laser products and cited failure to submit required reports including annual reports. The second letter approved an alternate means of safety in lieu of compliance with the requirement for a beam attenuator. However, you were clearly advised that all future products had to be in compliance with all other applicable requirements of the Federal regulations. An inspection on February 20, 1997, by Mr. Gary Zaharek of the Pacific Regional Staff of the Food and Drug Administration indicated that the required corrections had not been implemented, that annual reports had not been submitted, and that you declined to commit to any corrections.

Based on these findings, the CDRH declares that IDEC Corporation and IDEC/IZUMI Corporation have failed to conduct a testing program which ensures compliance with the applicable performance standard. The CDRH therefore, under authority of 21 CFR 1010.2(c), disapproves the testing and quality control program for their laser products.

This disapproval means that your firms are prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,

2. introducing or importing products into the United States (U.S.) commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and

3. introducing or importing into the U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U. S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 such that the CDRH can determine that IDEC Corporation of Sunnyvale, California and IDEC/IZUMI Corporation of Japan are in compliance with the Act, that the subject products comply with the performance standard, and that the testing programs are in accord with good manufacturing practices.

The CDRH will advise you whether your submittal is satisfactory.

You should submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Tsuneo Funaki, President
IDEC/IZUMI Corporation
7-31, Nishimmiyahara, 1-Chome
Yodogawa, Osaka 532
JAPAN